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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,486	05/11/2005	Takanori Matsuo	10525.0015-00000	7810
22852	7590	05/11/2010		
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EXAMINER EWOLDT, GERALD R	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 05/11/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/534,486

**Applicant(s)**

MATSUO ET AL.

**Examiner**

G. R. Ewoldt, Ph.D.

**Art Unit**

1644

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 15, 17, 19-31, 34, 35, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 10-12, 19-31, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 15, 17, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/12/10
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's amendment, remarks, and IDS filed 2/12/10 are acknowledged.
2. Claims 1-8, 10-12, 19-31, 34, and 35 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 9, 15, 17, 38, and 39 are under examination.

3. All objections to the claims have been withdrawn..
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9, 15, 17, 38, and 39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,617,440 (of record) in view of Ihara et al. (2001, of record) and Flyvbjerg et al. (2002, of record).

As set forth previously, The '440 patent teaches a screening method for a therapeutic substance (a compound which exhibits the ability to promote muscle growth) (see particularly column 8, lines 35-40) comprising cultivating a cell (the administered cell had to have been "cultivated") and comparing the expression of a gene in the presence or absence of a test compound. Said method further includes the assaying of mRNA expression (see particularly column 7, line 63 - column 8, line 13).

The reference differs from the claimed invention in that it does not teach comparing the expression of a gene encoding the protein of SEQ ID NO:2.

Ihara et al. teaches the protein of SEQ ID NO:2 (TSC-22), is associated with diabetes. In particular, the expression of the gene of SEQ ID NO:1 can be used as a marker for insulin expression. TSC-22 inhibits insulin expression such that a measure of TSC-22 expression can be used as a measure of insulin expression and the reduction of TSC-22 expression is an indication of increased insulin expression (see the entire Abstract).

Flyvbjerg et al. teaches that diabetic nephropathy in type 2 diabetic patients is a frequent complication; indeed, it is the most common cause of end stage renal failure in the Western world (see particularly page 3090, column 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the screening method of the '440 patent employing the measuring of the expression of the TSC-22 gene of Ihara et al. given the relationship of TSC-22 expression and insulin expression. Said method could be used as a method for screening test substances for their effect on TSC-22 expression as a measure of their efficacy as a therapeutic for the treatment of diabetes. Further, Flyvbjerg et al. teach that diabetic nephropathy in type 2 diabetic patients is a frequent complication; indeed, it is the most common cause of end stage renal failure in the Western world thus, treatments for diabetes would comprise needed treatments for one of the most common renal diseases.

Applicant's arguments, filed 2/12/10, have been fully considered but are not found persuasive. Applicant argues that in the method of the instant claims the insulin gene, or a gene under the control of the insulin promoter, is used as a reporter or indicator of change.

In the method of the combined references insulin would be used as a reporter replacing the myostatin reporter of the '440 reference. Note that there is no limitation that insulin expression can function as both an effector and reporter in the claimed method.

Applicant again raises the argument that the model of Ihara et al. is not an appropriate model for diabetic nephropathy. Specifically, Applicant argues that TSC-22 is implicated in renal disease regardless of diabetes or insulin status.

As set forth previously, Flyvbjerg et al. teaches that diabetic nephropathy in type 2 diabetic patients is a frequent severe complication. Thus, regardless of animal models employed, treatments for diabetes would be expected to reduce this complication in humans, i.e., simply treating the disease would reduce any complications of the disease. Accordingly, finding new treatments for diabetes would comprise an obvious way to find new treatments for renal disease of which diabetic nephropathy is the major one.

Additionally, the establishment of obviousness need not encompass the entire scope of that which is taught by the specification, or that which is claimed. It is enough that one embodiment, in this instance an embodiment encompassing a method for the identification of prophylactic or therapeutic substances for the treatment of diabetic renal disease, is obvious in view of the combined references.

Applicant argues that diabetes is not the disease targeted by the claimed screening method.

There is no limitation disclosed in the specification nor, more importantly, recited in the claims, excluding diabetic renal disease from the method of the instant claims.

6. No claim is allowed.

7. Regarding the European Communication submitted in the IDS of 2/12/10, there is no evidence that the Communication was publicly available as of its mailing date. Additionally, Applicant argues that the author is the Examiner at the European Patent Office, yet no Examiner has been listed as the author. Accordingly, the reference has again been lined through and has again, not been considered.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0841.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

Art Unit: 1644

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/G.R. Ewoldt/

G.R. Ewoldt, Ph.D.

Primary Examiner

Technology Center 1600